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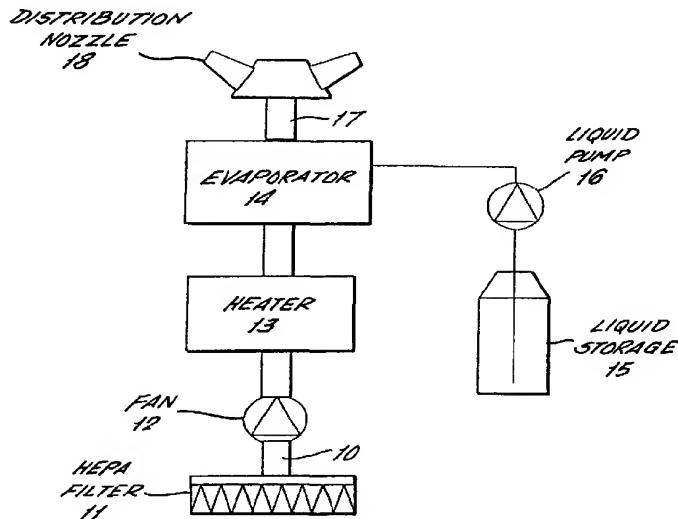
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(54) Title: METHODS AND APPARATUS FOR DECONTAMINATING ENCLOSED SPACES



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(57) Abstract: The disclosure relates to a portable apparatus for decontaminating an enclosed room or other space comprising a passageway (17) having an air inlet at one end and an outlet at the other end. A pump (12) to cause a flow of air through the passageway from the inlet to the outlet. A heater (13) to heat the air flowing through the passageway to a predetermined temperature, and a flash evaporator (14) in communication with the passageway. Liquid decontaminant is pumped (16) from a supply (15) of decontaminant to the evaporator (14) to be evaporated and for the evaporant to be delivered to the air flow in the passage (17) to flow in the air flow from the outlet to the rooms to be decontaminated. A universally rotating nozzle (18) is provided at the outlet to distribute the decontaminant containing air throughout the enclosure.

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## METHOD AND APPARATUS FOR DECONTAMINATING ENCLOSED SPACES

This invention relates to methods and apparatus  
5 for decontaminating enclosed spaces such as hospital  
wards and clean rooms in which a manufacturing or  
other processes take place in sterile conditions.

Vaporised aqueous solution of hydrogen peroxide  
10 has been used to decontaminate the internal surfaces  
of enclosures used for aseptic processing in the  
pharmaceutical industry since about 1990, but it has  
always been difficult to use the same technology to  
decontaminate larger enclosed volumes such as rooms.  
15

The conventional apparatus for decontaminating  
enclosures comprises a gas generator in a closed  
circuit including the enclosure such as described in  
US Patent 5,173,258. In this design the hydrogen  
20 peroxide and water vapours are produced by flash  
evaporation of an aqueous solution into a heated air  
stream, which then carried the gas to the space to be  
decontaminated. The air and mixture of gases then  
mixes with the air inside the chamber before being  
25 returned to the gas generator, where the gas is  
decomposed, dried, heated and more liquid is flash  
evaporated and the air mixture is returned to the  
chamber.

30 The processes performed on the returned gas are  
complex, and include the steps of decomposing the gas,  
drying and re-heating. This complete process was  
considered necessary because it was understood that  
the hydrogen peroxide gas decomposed according to a  
35 half-life rule and hence to maintain an adequate

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concentration inside the chamber a circulating system  
that decomposed the gas was thought to be necessary.  
Recent work by Watling, ISPE Conference Zurich,  
September 1999 has shown that the gas does not  
5 decompose but is stable. It is therefore not  
necessary to remove the returning gas from the  
chamber.

S.S. Block reports in the 5th Edition of  
10 Disinfection, Sterilisation and Preservation page 189  
that a 3% hydrogen peroxide aqueous solution gives a  
log 8 reduction of Staphylococcus aureus in under 20  
minutes. A slower rate of deactivation has been found  
in experimental work when exposing Staphylococcus  
15 aureus to gas generated from 35% solution, when the  
process was operated at a temperature below the dew  
point thus causing condensation. Under these gassing  
conditions the first droplets of dew form on the  
organism at a much higher concentration than that of  
20 the original liquid, typically about 65% w/w, the  
exact value depending on the moisture content of the  
carrier gas.

As stated above, in the conventional system the air in  
25 the chamber to be decontaminated is dried prior to  
injecting the decontaminating gas. This is done either  
to allow a high level of gas concentration to be  
achieved before the onset of condensation, or to  
operate the process avoiding condensation maintaining  
30 the gas in a dry state. The vapour pressure equations  
for hydrogen peroxide and water may be used to  
calculate the concentration of the hydrogen peroxide  
and water vapour that will cause condensation and  
hence may be used either to avoid the conditions that

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will cause the onset of condensation or to calculate the concentration of any condensate that may be formed as a result of passing the flash evaporated vapours into the sealed enclosure. If the RH in the chamber is  
5 high the condensation will form quickly but as a relatively weak solution. Evaporating 35%w/w hydrogen peroxide into a chamber at 20°C and 85%RH will cause the condensate to form at in excess of 6% w/w, although the concentration of the vapour will be about  
10 120 ppm. It is well known that 6% hydrogen peroxide is active against microorganisms and will cause bio-deactivation of surfaces. If it is intended to operate a process where condensation is formed it is therefore not necessary to reduce the humidity in the chamber  
15 under normal operating conditions as the RH will be less than 85% and hence the condensation will form at a concentration greater than 6%. The same is not true when operating a process that is intended to avoid condensation, in such a process it is essential to  
20 ensure that the moisture content of the air inside the enclosed space at the start of the process is low.

It is believed that the difference between the liquid process as reported by Block and a gaseous dew  
25 process is the rate of delivery of the hydrogen peroxide condensation. It follows that using a standard recirculating gas generator placed outside the space to be bio-decontaminated; there may not be an adequate evaporation capacity to achieve a  
30 sufficiently high condensation rate to deactivate the organism inside the chamber. The deactivation process may be enhanced by the use of mixtures of chemicals but the principal of the rate of delivery still remains. Whilst for a dry gas process the rate of

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delivery of hydrogen peroxide and water vapour are not so critical it is still important to evaporate the liquid as fast as is practical as this will shorten the time required to raise the gas concentration and  
5 achieve a satisfactory bio-decontamination.

An analysis of the equations governing the vapour pressure of water and hydrogen peroxide by Watling et al and published in the PDA Journal of Science and  
10 Technology Nov/Dec 2002 vol 56, No 6 291-299, shows that the gas concentration inside a chamber may be raised to the dew point by passing flash evaporated vapour into the sealed enclosure, but as soon as the dew point is reached condensation will form at a  
15 higher concentration than the evaporated liquid thus reducing the gas concentration. The gas concentration will continue to fall as more liquid is evaporated until the equilibrium vapour pressure for the  
20 evaporated liquid is reached at the temperature of the chamber.

There are two views about the mechanisms involved in the bio-decontamination using hydrogen peroxide and water vapour. The first is that it is important to  
25 ensure that the gas remains in the dry state and the second that condensation is essential. It has been well established that dry hydrogen peroxide gas at elevated temperatures will bio-deactivate micro-organisms, and the same dry process has been shown to work at room temperatures. The condensation process in  
30 which the gas concentration is raised to the dew point and condensation is allowed to form appears to be faster at room temperatures.

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The apparatus and method described in the present invention will work equally well with both the dry and condensation processes. When operating a dry process it is essential to monitor the water and hydrogen peroxide concentration in the gaseous phase to ensure that they remain below the saturated vapour concentrations. When operating a condensation process it is helpful to have an indication of the point during the cycle when condensation starts to form and the subsequent rate of formation. A technique and apparatus to make such a measurement of condensation is described patent application UK 0291983.1

An ideal bio-decontamination cycle is in three phases. The first phase is to bring all of the equipment to thermal stability but may also be used to adjust the relative humidity in the chamber to a pre-set level, the second is used to raise the gas concentration to the required level and maintain that concentration for a sufficient length of time to achieve the required level of bio-decontamination, and the third and last phase to reduce the concentration of the sterilant in the enclosed space to a predetermined value.

This invention provides an apparatus and method for decontaminating an enclosed space comprising a passageway having an air inlet at one end and an outlet at the other end, means to cause a flow of air through the passageway from the inlet to the outlet, means to heat the air flowing through the passageway to a predetermined temperature, evaporator means in communication with the passageway, means to delivery liquid decontaminant from a supply of decontaminant to the evaporator means to be evaporated thereby and for

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the evaporant to be delivered to the air flow in the passage to flow in the air flow from the outlet to the rooms to be decontaminated.

5        By placing the gas generator inside the room and simply heating the carrier gas and then evaporating this sterilant into the air stream it is possible to use the available energy much more efficiently. The increase in efficiency is derived from the removal of  
10      the system for decomposing and drying the carrier gas, and also because there is no need for any pipe work to transport the carrier gas and decontaminant from an external generator.

15       This increased efficiency provides more energy for the primary function of heating the carrier gas and flash evaporating the liquid. The efficiency increase is so great as it allows a trebling of the rate of flash evaporation from the same energy source  
20      and hence the rate of increase in the gas concentration or the achievable rate of formation of condensation once the dew point has been reached is also trebled.

25       The simplified design is also much smaller and lighter than a conventional gas generator and hence considerably less expensive to manufacture. It is therefore realistic to place a number of such devices inside a sealed enclosure to be decontaminated. This  
30      reduction in size and weight makes the apparatus portable and hence makes it practical to use the same apparatus to bio-decontaminate a number of facilities either on the one site or at different locations. As stated above it is important to make measurements of

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the hydrogen peroxide and water vapour concentrations. To satisfy this requirement an instrument module that is placed inside the enclosed space has been devised that will also link back to the control system that is 5 external to the enclosed space. Provision has been made within the control systems both at the gas generator(s) and the instrument module to connect a number of condensation sensors so that the process may be operated either as a dry gas or as a saturated 10 vapour process

Each simplified generator will have its own control system, which is linked to a control box external to the room and connected by a single control 15 cable. By using a central control system, such as a laptop computer, it is possible to control a number of generators that are linked together from outside the enclosed space. With the present arrangement it is possible to control eight generators from a single 20 laptop, should a larger number be required a second computer would be needed. It is also possible to control multiple aeration units and dehumidifiers from the same laptop computer.

25 Because the apparatus is portable and may therefore be used at different sites in order to ensure that the apparatus does not carry contamination from one location to another it is essential that all of the external and internal surfaces are bio- 30 decontaminated during the gassing cycle. To achieve this objective components have been mounted in such a way to ensure that they are exposed to the sterilising gas. The tubular steel frame has been sealed and the control box is purged with the sterilising gas drawn

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from the room. Tests have been performed to check that following a bio-decontamination cycle all of the surfaces of the apparatus have been rendered safe.

5       The following is a description of some specific embodiments of the invention, reference being made to the accompanying drawings, in which:

10      Figure 1 is a wholly diagrammatic view of an apparatus for generating and delivering an air flow containing an evaporated decontaminant to an enclosed space;

15      Figure 2 is a similar view to Figure 1 showing the components of the apparatus including the evaporator, liquid sterilant supply and outlet nozzle in greater detail;

20      Figure 3 is a perspective view of a portable unit embodying the apparatus of Figures 1 and 2;

Figure 4 is an exploded view of the unit of Figure 5;

25      Figure 5 is a plan view of the evaporator;

Figure 6 is a cross-sectional view on the line 5-5 of Figure 5;

30      Figure 7 is a cross-sectional view of an alternative form of evaporator;

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Figure 8 is a perspective view of a control box for the apparatus of Figures 3 and 4 with a lid of the box shown open;

5       Figure 9 is an exploded view of a monitoring unit for use in conjunction with the apparatus of Figures 3 and 4; and

10      Figures 10 and 11 show further embodiments.

The gas generator apparatus will be described firstly with reference to Figures 1 and 2. Room air, which may or may not already contain previously supplied hydrogen peroxide and water vapour, is drawn into an inlet conduit 10 through a HEPA filter 11 by a variable speed motor driven fan 12. The HEPA filter 11 removes any particles from the air stream to ensure that the delivered air is of the correct quality when the generator is used in a clean room. The conduit 15 delivers the air to a heater 13 where the temperature is raised to a predetermined level as described below. The heated air then passes into an evaporator 14 where a liquid sterilant comprising aqueous hydrogen peroxide is flash evaporated. By way of example, the 20 sterilant may comprise an aqueous solution containing 30 to 35% hydrogen peroxide. If the sterilant includes peracetic acid, the proportion of hydrogen peroxide can be reduced to 15% with 0.5% peracetic acid and a balance of water. In practice the heater 25 13 and the evaporator 14 are combined in a single unit as shown in Figures 2 to 7 to which reference will be made later. The physical shape and dimensions of the 30 combined heater/evaporator are designed to control the

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energy balance between that used to heat the carrier gas and that used for flash evaporation.

A supply of aqueous hydrogen peroxide liquid is  
5 stored in a container 15 and is pumped to the evaporator 14 by a liquid pump 16. The carrier gas and vapours are delivered from the evaporator through a conduit 17 to a distribution nozzle 18 for delivery of the sterilant vapour to the space to be  
10 decontaminated. The liquid container is demountable from the frame 19 to reduce the weight of the unit and make it more easily hand carried.

Figures 3 and 4 show a practical embodiment in  
15 which the gas generator apparatus is supported in an tubular steel framework 19 for ease of movement. The apparatus is light enough to be carried by the user and as can be seen in Figure 4 can have caster wheels 20 to enable it to be easily manoeuvred into position.  
20 The tubular framework is sealed to prevent any contamination being introduced to the enclosure by the frame. Ideally, the apparatus should not be placed inside a housing unit. Any covering of the apparatus would restrict the sterilant gas movements around and  
25 through the apparatus, which is essential to ensure that the apparatus itself is also surface decontaminated because otherwise it may contaminate the area in which it is placed. Figures 3 and 4 also show the enclosed control box 70 for the apparatus  
30 which will be described in greater detail below.

Figure 3 shows the outlet nozzle in greater detail. The nozzle has a motorised power unit 18a which rotates the nozzle assembly about a vertical

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axis. The nozzle assembly includes a laterally extending arm 18b having an enclosed drive for rotating the nozzle tip 18c about a horizontal axis to provide a universal discharge of heated air/hydrogen peroxide sterilant vapour around the room or other enclosure. The motor and nozzle assembly are formed as a unit and may be detached at the coupling 18d shown in Figure 4 from the outlet of the evaporator and dismounted from the frame to be transported independently of the gas generator unit. Multiple units may be provided as necessary and separate fan units may also be provided to circulate the sterilant atmosphere throughout the room or enclosure.

15

An ideal decontamination cycle may have three distinct phases. In the first, optional phase the relative humidity in the room or other enclosure is adjusted to a pre-set level. In the second phase the gas concentration of sterilant gas is raised to form a required layer of overall surfaces in the enclosure condensation for a sufficient length of time to achieve the required level of decontamination. In the third and last phase the sterilant is removed from the enclosure. This is achieved using the room aerator system described and illustrated in our International Patent Application No. WO 02/11864.

30

If a HVAC system is available for the room or enclosure then this may be used to achieve the required level of relative humidity at the start of the process, and if the HVAC exhausts to a safe area to remove the sterilant at the end. Alternatively a portable dehumidifier may be used to adjust the

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initial relative humidity and a catalytic scrubber used to circulate the gas to remove the sterilant.

In the decontamination cycle referred to above  
5 the initial phase of treatment in the adjustment of the relative humidity in the room or chamber may be omitted and the process commenced at the current prevailing conditions in the enclosure since the relative humidity in the enclosure would normally be  
10 well below dew point and so a considerable amount of sterilant/water vapour would need to be generated in the enclosure before condensation would occur.

Reference is now made to Figures 5 and 6 which  
15 illustrate the combined heater/evaporator 14/15 in greater detail. The heater/evaporator comprises a cast cylindrical aluminium block 30 which is mounted framework 19 with the axis of the block extending vertically. The lower end of the block has a shallow cylindrical recess 31 and a circular base plate 32 is attached to the periphery of the block extending across the recess by screws (not shown) the base plate 32 has a central aperture 33 in which the end of the inlet conduit 10 is mounted to deliver a supply of air  
20 to the recess in the block.  
25

The upper end of the block also has a cylindrical recess 34 and a central top plate 35 is mounted on the periphery of the block over the recess by set screws  
30 36. The top plate 35 has a central aperture 39 in which an outlet conduit 40 from the block is mounted.

The block is formed with a central cylindrical cavity 37 extending into the block from the upper end

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thereof in which the outlet conduit 40 extends stopping short of the bottom of the cavity. The block 30 has a multiplicity of axially extending passageways 38 adjacent the outer surface of the block  
5 and spaced around the block leading from the lower recess 31 and the block upper recess 34 for flow of air from the bottom recess to the top recess from where the air can flow into the cavity 37 and thence into the outlet conduit 40. The liquid sterilant  
10 from the storage container 15 is delivered via one or more inlet conduits 41 which extend through the top plate 35 adjacent to the outlet conduit 40 and also lead into the cavity 37 in the block and again stop short of the bottom of the cavity. A second such  
15 inlet conduit 41 is shown in dotted outline and preferably three such conduits are provided at spaced locations around the inlet conduit.

The body 30 is encircled by a cylindrical jacket  
20 in which an electrical resistance heater 42 is mounted for heating the body 30 to a requisite temperature to pre-heat the airflow through the block and also to ensure that sterilant delivered by the conduit 14 to the bottom of the cavity 37 of the block is flash  
25 evaporated from the bottom of the cavity to produce a vapour which is entrained in the flow of air through the flow of heated air through the outlet conduit 40 for delivery into the room to be sterilised.

30 The heating unit of the heater-evaporator is coupled to the control unit to the apparatus and a temperature probe 44 is mounted in a radial drilling  
45 in the body 30 below the cavity 37 to measure the temperature of the body for adjusting, through the

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control unit, the power supply to the resistance heating element to enable the body to be maintained at a requisite temperature for pre-heating the air flowing through the body and flash evaporating the  
5 sterilant delivered to the body.

Figure 7 of the drawings shows an alternative form of heater 13 in which the outlet from the fan 12 is coupled to an inlet 50 to a lower chamber 51 containing an electrically powered air heater 52. At the upper end of the chamber 51 there is an annular evaporator lock 53 having a central port 54 for gas flow and an evaporator plate 55 is located on top of the block. The block has a spirally wound heating element 56 embedded adjacent the surface of the block.  
10 Thus the heater 52 can be used to raise the temperature of the air flowing through the device to one level and the second heater 56 can be used to maintain the surface of the evaporator plate at the  
15 requisite temperature for flash evaporation of an aqueous solution of hydrogen peroxide.  
20

The heater has an upper chamber 57 in which an outlet conduit 58 is mounted having ports 59 spaced around the conduit through which air can enter the conduit from the upper chamber as indicated by the arrows. The lower end of the conduit is closed by an air deflector 61 which partially overlies the evaporator plate and causes the air flow emerging  
25 from the port 54 in the evaporator heater to disperse outwardly over the evaporator plate before flowing upwardly and hence through the port 59 into the inlet conduit. Delivery tubes for aqueous hydrogen peroxide extend downwardly through the upper chamber 57 to stop  
30

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just short of the surface of the evaporation plate to drip aqueous hydrogen peroxide onto the plate which flash evaporates and is entrained in the air flow over the plate which passes upwardly into the outlet conduit 58. The arrangement is otherwise similar to that of Figures 3 and 4.

Reference is now made to Figure 8 of the drawings which shows the control box of the gas generator of Figures 3 and 4 in greater detail. The control box 10 comprises a casing 70 having a lid 71 shown in the open position in Figure 8. The fan 11 which is of the centrifugal type is mounted in the upper end of the box and has an upwardly facing mounting plate 72 formed with an outlet port 73 to receive the evaporator 13, 14 with the inlet to the evaporator in communication with the port 73.

A liquid pump 74 is mounted on one side of the 20 box powered by an electric motor for delivering aqueous hydrogen peroxide to the evaporator. A mains cable connection for the unit for the various motors and other devices requiring power supply is indicated at 75. The cable also provides couplings to the 25 controllers 76 for the unit which are mounted on the inside of the lid 71.

To ensure that contamination does not reach the 30 enclosure from the interior of the control box for the gas generator, a fan 77 is mounted on one side of the control box to deliver air carrying sterilant from the surrounding atmosphere in the enclosure through the control box to sterilise the interior surfaces of the control box.

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Reference is now made to Figure 9 of the drawings which shows in exploded form a monitoring unit for monitoring air temperature, gas concentration and humidity in the enclosure. The monitoring unit 5 comprises a box 80 to receive the monitoring equipment and mounted on wheels 81 to enable the box to be readily manoeuvred around the enclosure and also moved from side to side where it is to be used. The box has a lid 82 formed with inlet and outlet ports 83, 84 respectively. The inlet port has a motor driven fan 85 disposed below the port to draw in air from the enclosure containing the dispersed sterilant to cause an air flow through the elements in the box to sterilise the interior surfaces of the box and thereby 10 to ensure that the room or other enclosure is not contaminated by anything within the interior of the 15 box.

The apparatus described particularly with 20 reference to Figures 3 to 9 is intended to be readily portable or transportable from room to room where it is to be used. It provides a source of heated air carrying hydrogen peroxide vapour sterilant directly 25 into the room and distributes the air flow throughout the room until condensation occurs on all surfaces within the room. No external pipework connections are required to pass through walls of the room just power supply and control cables for the apparatus. No 30 special installation requirements arise as in conventional gas generator circuit systems as referred to earlier.

Thus each of the components of the equipment required to sterilise a room, that is the gas

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generating apparatus, the gas distribution system, the instrument-module, the dehumidifier and the aeration unit are all manufactured such that they can readily be carried by a single person.

5

Reference is now made to a further form of apparatus in accordance with the invention shown in Figure 10. The apparatus is mounted on a mobile trolley and comprises a gas generator 100. Air is drawn in through a HEPA filter 101 by a fan 102 and passed into a vaporiser 103. Inside the vaporiser the air is first heated by a heater (not shown) and then passes over an evaporation plate (also not shown). A pump 105 delivers liquid sanitant from a sanitant bottle 106 in the form of droplets onto the evaporation plate from which it is flash evaporated. The heated air carrying the sanitant vapour is passed to a distribution plenum 108 and exits to the room at high velocity through one or more nozzles 109.

20

Provision is made either to connect a number of optical type condensation monitors 120 directly to the gas generator and hence to a control module 121 (see Figure 11), or the monitors may be connected directly to the control module. The optical condensation monitors measure the layer of condensation as it builds up on a surface or surfaces of the monitor. Connecting condensation monitors to the gas generator has the advantage of reducing the number of connections to the control module, especially when a number of gas generators are used.

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The condensation monitors are placed around the room at the locations where the rate of condensation is the lowest.

5       A complete multiple installation is shown in Figure 11, with three gas generators 100 each with eight condensation monitors 120. Also connected to the control system is an aeration unit 122 used to remove the gas at the end of the cycle and the  
10      dehumidifier 123. A separate instrument module 124 is also shown which has additional instrumentation to measure the gas concentration and the RH within the room. A single communications cable connects 24 all of the components to the control module.

15           The normal technique to establish if a decontamination process has been successful is to place Biological Indicators (BIs), in those parts of the chamber where it is the most difficult to achieve a kill. It is often undesirable or not permitted to place BIs in a room, but it is necessary to know that deactivation to the required level has been achieved. To overcome this difficulty condensation monitors may be used to establish that the mass and the rate of formation of condensate are sufficient to achieve deactivation of the microorganisms on the surfaces. It has been well established that once the required conditions have been achieved that the "D" value for the most resistant organisms is about two minutes.  
20           Therefore an exposure of the organisms under the correct conditions for twelve minutes will achieve a log 6 reduction in the count of viable organisms.  
25  
30

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Satisfactory decontamination will only be achieved in a room if a sufficiently high rate of liquid sanitant vapour is delivered into the room to provide an adequate rate of formation of condensation.

5      But to be assured that decontamination has been achieved it is necessary to measure the condensation levels with time in multiple locations in the room. The data from the condensation monitors together with the information from the other instruments in the room

10     may then be used to establish that a satisfactory deactivation cycle has been completed.

The condensation sensors may be used in one of two ways. The first is to measure and then control the level of condensation by adjusting the liquid evaporation rate and the second is simply to use the monitor as a switch. When used as a switch it simply gives a signal when an adequate amount of condensation has formed and the process is then considered to be complete or allowed to dwell in that state giving a sufficient period during which the organisms are killed. There is a further variation to the "switch" method in which two sensors are used at each location set at different levels of condensation. The first indicates when condensation has started and the second when the level of condensation is sufficient to have caused a satisfactory level. It may then be necessary to have a "dwell" period during which the kill occurs.

30      The condensation monitors of the above apparatus are optical devices which measure the layer of condensation. An electronic device may be used instead that gives a switch signal when a known level of condensation has arrived. The switch level depends

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on the construction of the sensor plate. Sensor plates are single use disposable items and hence are inexpensive. The plates plug into a box which may be placed at a remote location within the room.

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CLAIMS:

1. A method of decontaminating an enclosed space comprising the steps of creating within the enclosed  
5 space hydrogen peroxide/water vapour from an aqueous solution of hydrogen peroxide, generating a flow of heated air within the enclosed space, introducing the hydrogen peroxide/water vapour into the flow of heated air to be carried by the air flow, distributing the  
10 air flow carrying the hydrogen peroxide/water vapour throughout the enclosed space and over any surfaces in the enclosed space for a period of time sufficient to achieve bio-decontamination and then removing the hydrogen peroxide vapour from the enclosed space.

15

2. A method as claimed in claim 2, wherein hydrogen peroxide/water vapour is added to the flow of heated air circulated in the enclosure until the dew point of the vapour is reached and condensation of hydrogen  
20 peroxide/water vapour on the surfaces of the enclosure takes place following which the hydrogen peroxide is removed from the enclosed space.

25 3. A method as claimed in claim 2, wherein the measurement of the condensation of vapour is measured by a monitor and when the condensation has reached a requisite level, air flow containing hydrogen peroxide/water vapour is terminated.

30 4. A method as claimed in claim 2 or claim 3, wherein condensation is measured in the enclosure at a number of locations by condensation monitors to ensure that condensation has taken place throughout the enclosure.

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5. A method as claimed in claim 1, wherein air carrying hydrogen peroxide/water vapour is introduced into the enclosure until a predetermined concentration of hydrogen peroxide/water vapour in the atmosphere in  
5 the enclosure has been reached after which introduction of the air is terminated and the hydrogen peroxide is removed.

10 6. A method as claimed in claim 5, wherein biological indicators are used in the enclosure to determine when the concentration of hydrogen peroxide/water vapour in the atmosphere in the enclosure has reached the requisite level following which the hydrogen peroxide is removed.  
15

7. A method as claimed in any of the preceding claims, wherein the heated air carrying hydrogen peroxide/water vapour is delivered as a jet within the enclosure.  
20

8. A method as claimed in claim 7, wherein the heated air carrying hydrogen peroxide/water vapour is delivered in a universally rotating jet to distribute the vapour throughout the enclosure.  
25

9. A method as claimed in any of the preceding claims, wherein one or more fans are provided spaced from the delivery of air carrying hydrogen peroxide/water vapour into the enclosure to deliver air carrying the vapour to remote locations of the enclosure from said source.  
30

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10. A method as claimed in any of the preceding claims, wherein the vapour of hydrogen peroxide and water also contains peracetic acid.
- 5      11. A method as claimed in claim any of claims 1 to 9, wherein the solution from which the hydrogen peroxide/water vapour is produced contains 30 to 35% hydrogen peroxide and a balance of water.
- 10     12. A method as claimed in claim 10, wherein the solution from which the hydrogen peroxide solution is produced comprises 15% hydrogen peroxide, 0.5% peracetic acid and a balance of water.
- 15     13. A method as claimed in any of the preceding claims, wherein hydrogen peroxide is removed by circulating the air containing hydrogen peroxide over a catalyst.
- 20     14. A method as claimed in any of claims 1 to 8, wherein the hydrogen peroxide is removed from the enclosure using the heating/ventilation air conditioning system for the room.
- 25     15. A method as claimed in any of the preceding claims, wherein a plurality of heated air flows are provided to which the hydrogen peroxide/water vapour is added to provide a plurality of flows of heated air carrying hydrogen peroxide/water vapour at different locations in the enclosure.
- 30
16. A method as claimed in any of the preceding claims, wherein the method is controlled from outside the enclosure.

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17. A method as claimed in any of the preceding claims, wherein the air is dehumidified to reduce the relative humidity in the enclosure to a predetermined level prior to delivering heated air containing  
5 hydrogen peroxide/water vapour to the enclosure.

18. A method as claimed in claim 17, wherein the air is dehumidified using an air conditioned system for the enclosed space.  
10

19. A method as claimed in any of the preceding claims, wherein a portable apparatus is used in the enclosure having a duct with a fan for delivering air through the duct, a filter for filtering air entering the duct, a heater for heating air passing through the duct and means for delivering hydrogen peroxide/water vapour to the air passing through the duct and a nozzle for delivery of air carrying hydrogen peroxide/water vapour from the duct, the nozzle being rotated  
15 universally to distribute the hydrogen peroxide/water vapours throughout the enclosure, circulation of air carrying the hydrogen peroxide/water vapour through  
20 the duct causing decontamination of the duct.

25 20. An apparatus for decontaminating an enclosed space comprising a duct to be positioned within the enclosed space having an inlet end and an outlet end, a fan for causing air to flow from the enclosed space through the duct, a filter for filtering air at the inlet end of the duct, means for delivering aqueous hydrogen peroxide solution to a heater to flash evaporate the aqueous hydrogen peroxide to produce hydrogen peroxide/water vapour which is entrained in  
30 the air flow passing through the duct, a nozzle at the

- 25 -

outlet end of the duct and means to rotate the nozzle universally to deliver hydrogen peroxide/water vapour throughout the enclosure, all internal and external surfaces of the apparatus open to the enclosure being  
5 exposed to the hydrogen peroxide/water vapour carrying air in the enclosure to decontaminate the surfaces.

21. An apparatus as claimed in claim 20, wherein the components of the apparatus are mounted in a support  
10 for transport of the apparatus.

22. An apparatus as claimed in claim 21, wherein the apparatus is a self-contained unit which is mobile or portable for movement from location to location where  
15 it is to be used.

23. An apparatus as claimed in claim 22, wherein the supply of hydrogen peroxide/water vapour and/or the nozzle and means to rotate the nozzle are readily removable for transport of the apparatus.  
20

24. An apparatus as claimed in any of the preceding claims including a control box for controlling operation of the apparatus, wherein means are provided  
25 for delivering air carrying hydrogen peroxide/water vapour from the atmosphere in the enclosure around the control box through the control box to decontaminate inner surfaces of the control box.

30 25. An apparatus as claimed in any of the preceding claims including a separate monitoring unit for monitoring the temperature of the atmosphere in the enclosure and the concentration of hydrogen peroxide/water vapour in the atmosphere, wherein means are

- 26 -

provided for delivering a flow of air carrying hydrogen peroxide/water vapour through the enclosure of the monitoring unit to decontaminate interior surfaces of the monitoring unit.

FIG. 1.

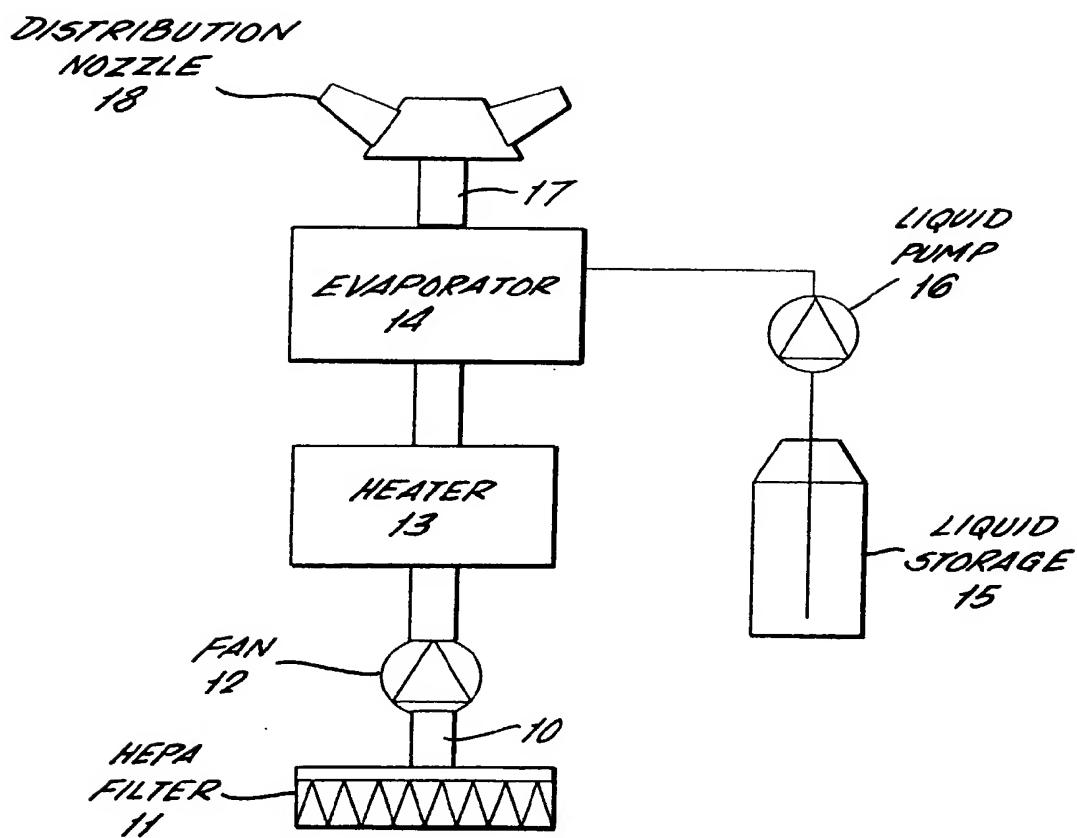


FIG. 2.

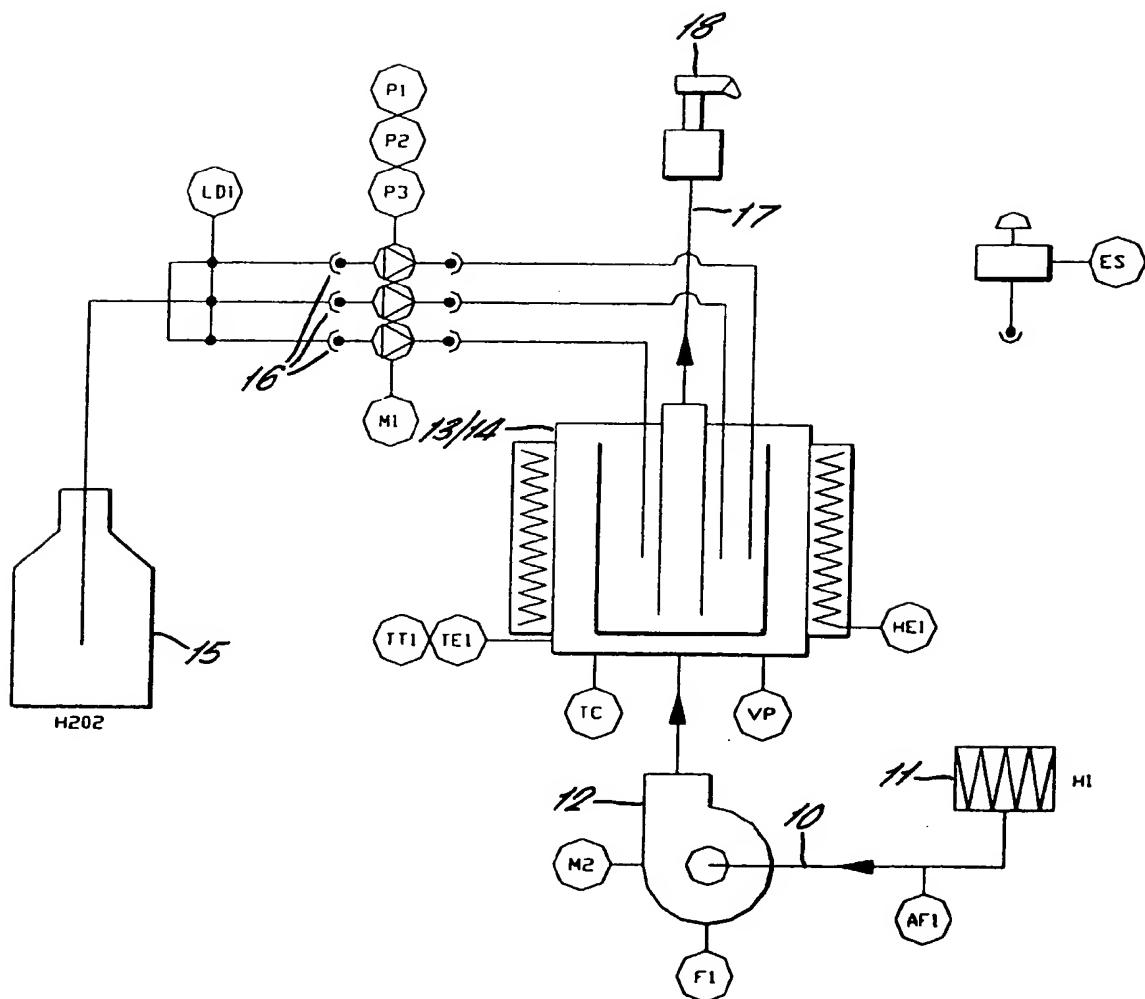


FIG. 3.

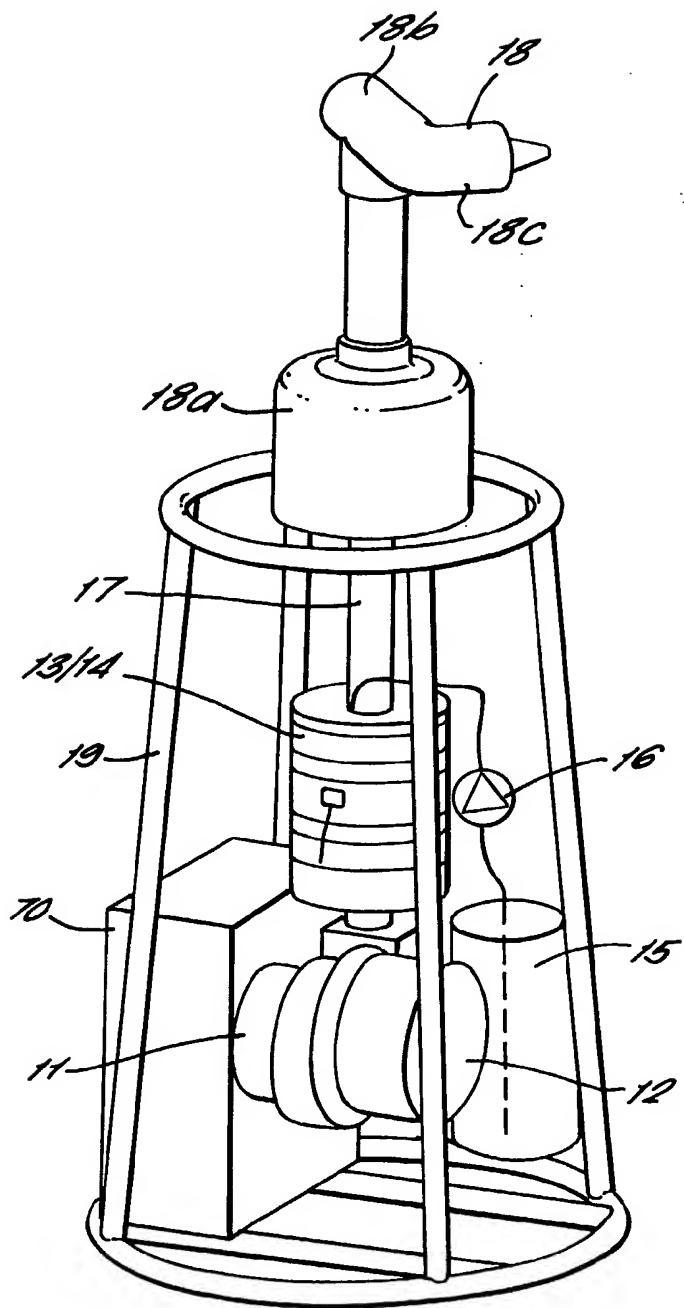


FIG. 4.

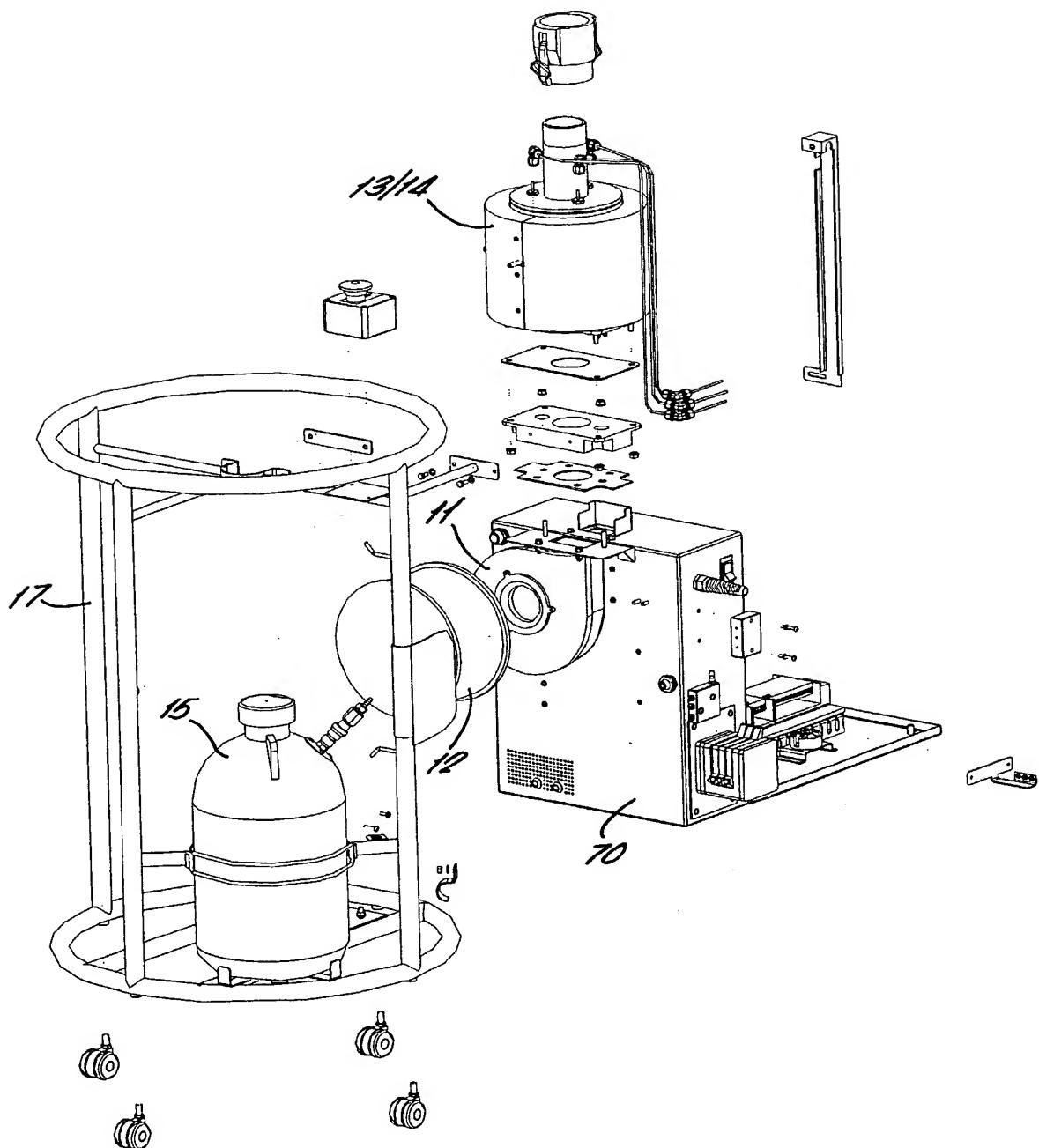


FIG. 5.

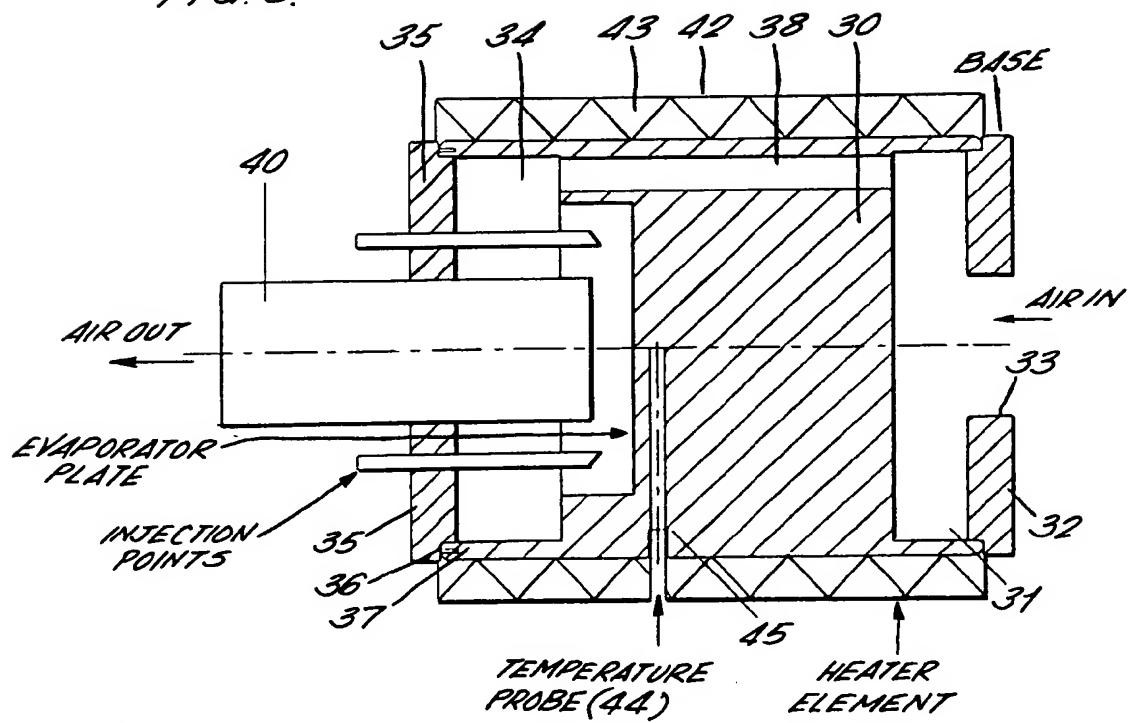


FIG. 6.

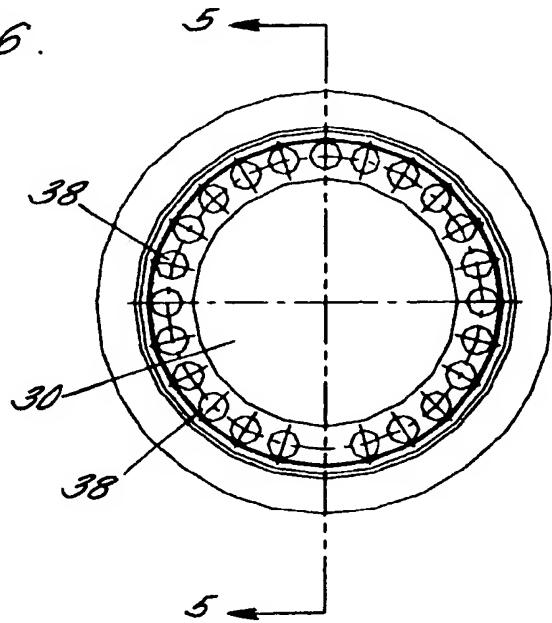
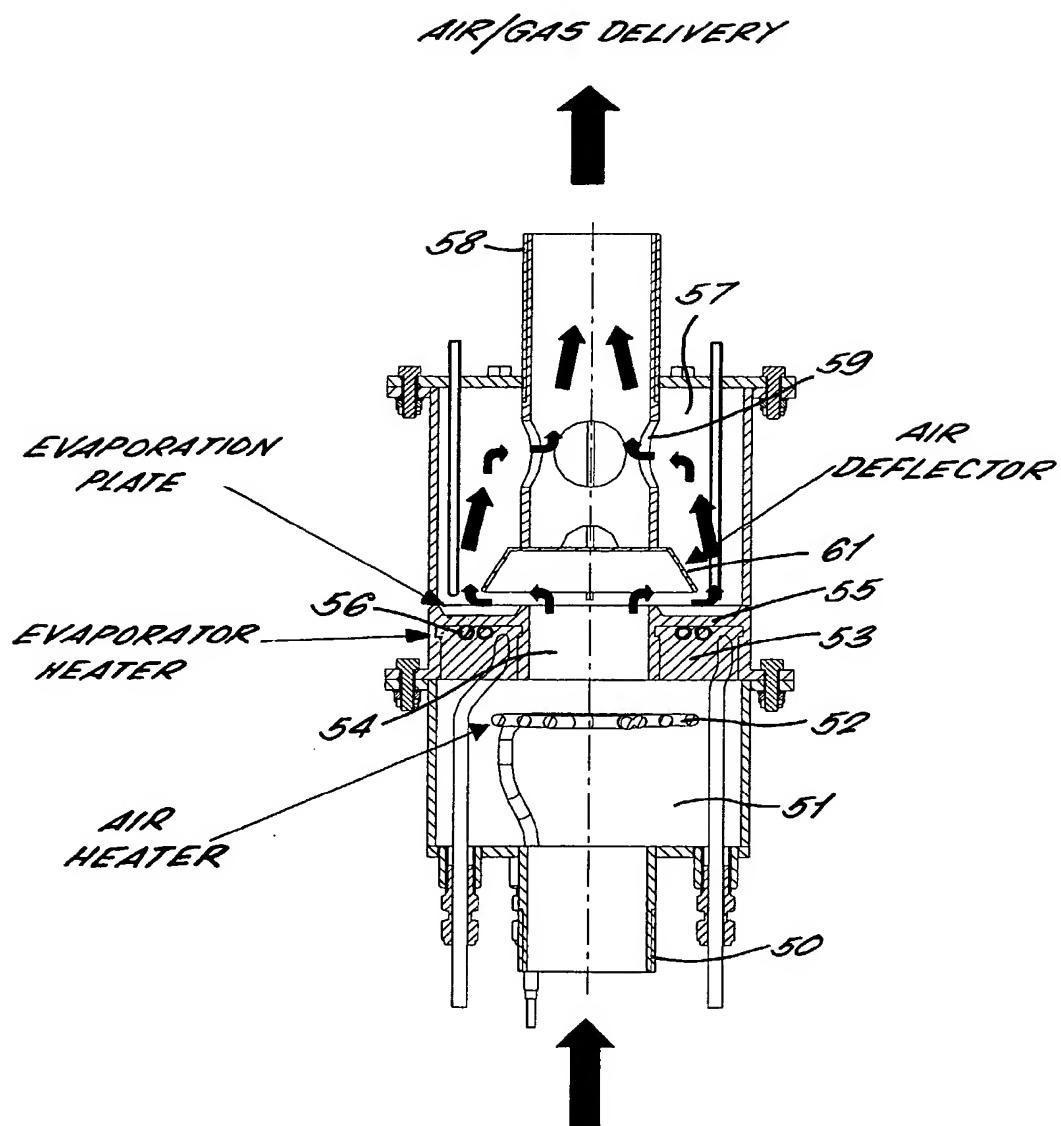
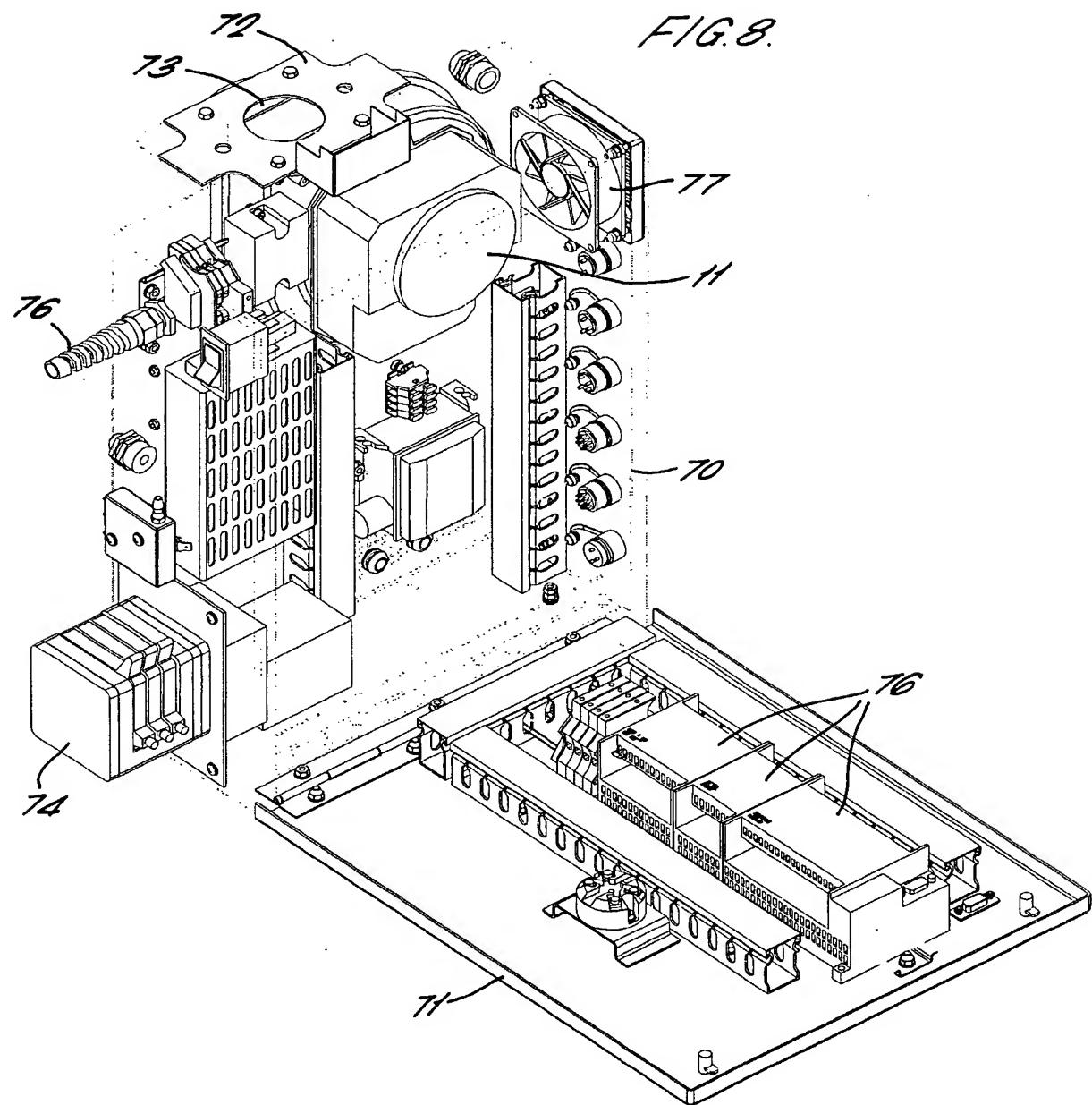


FIG. 7.





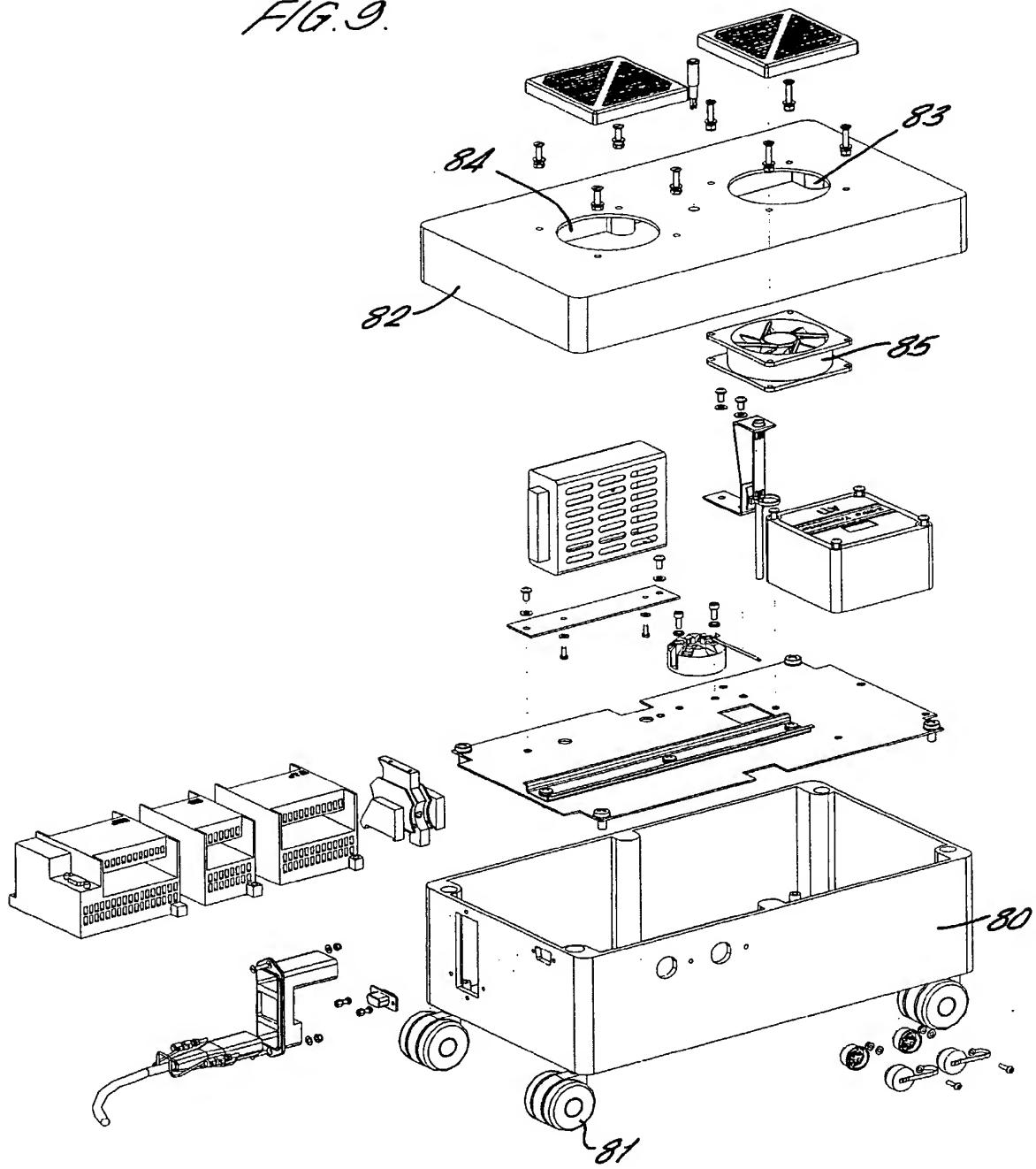
*FIG. 9.*

FIG. 10.

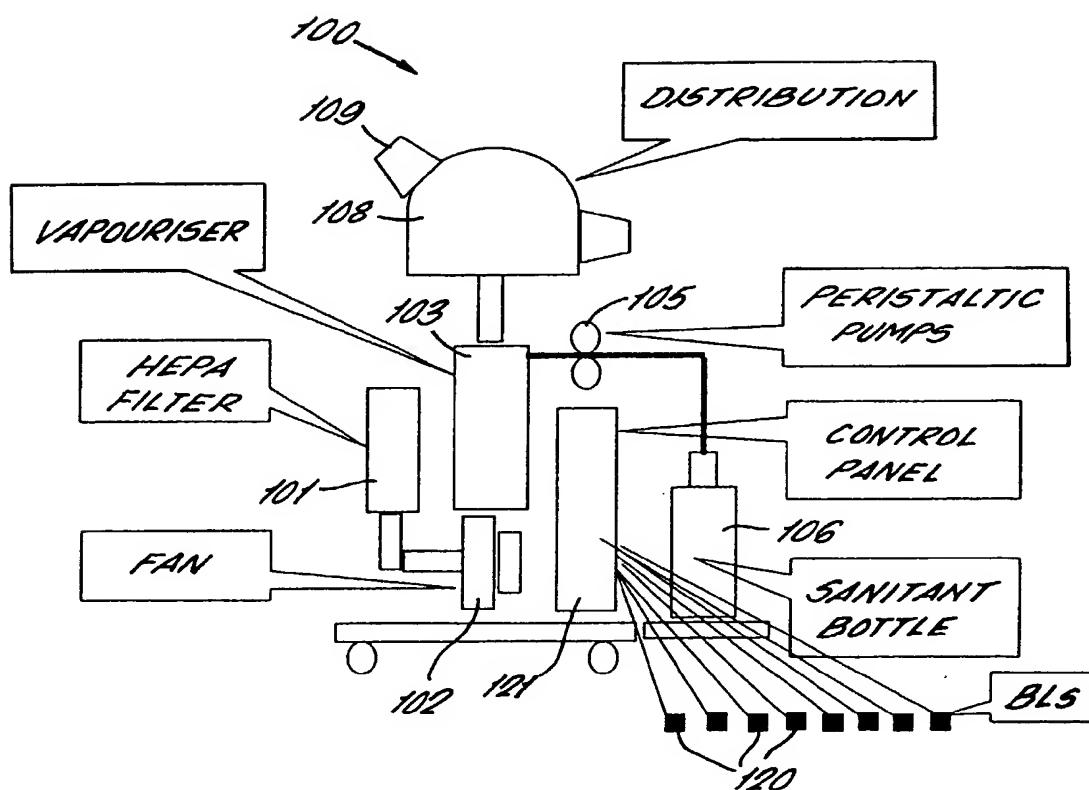
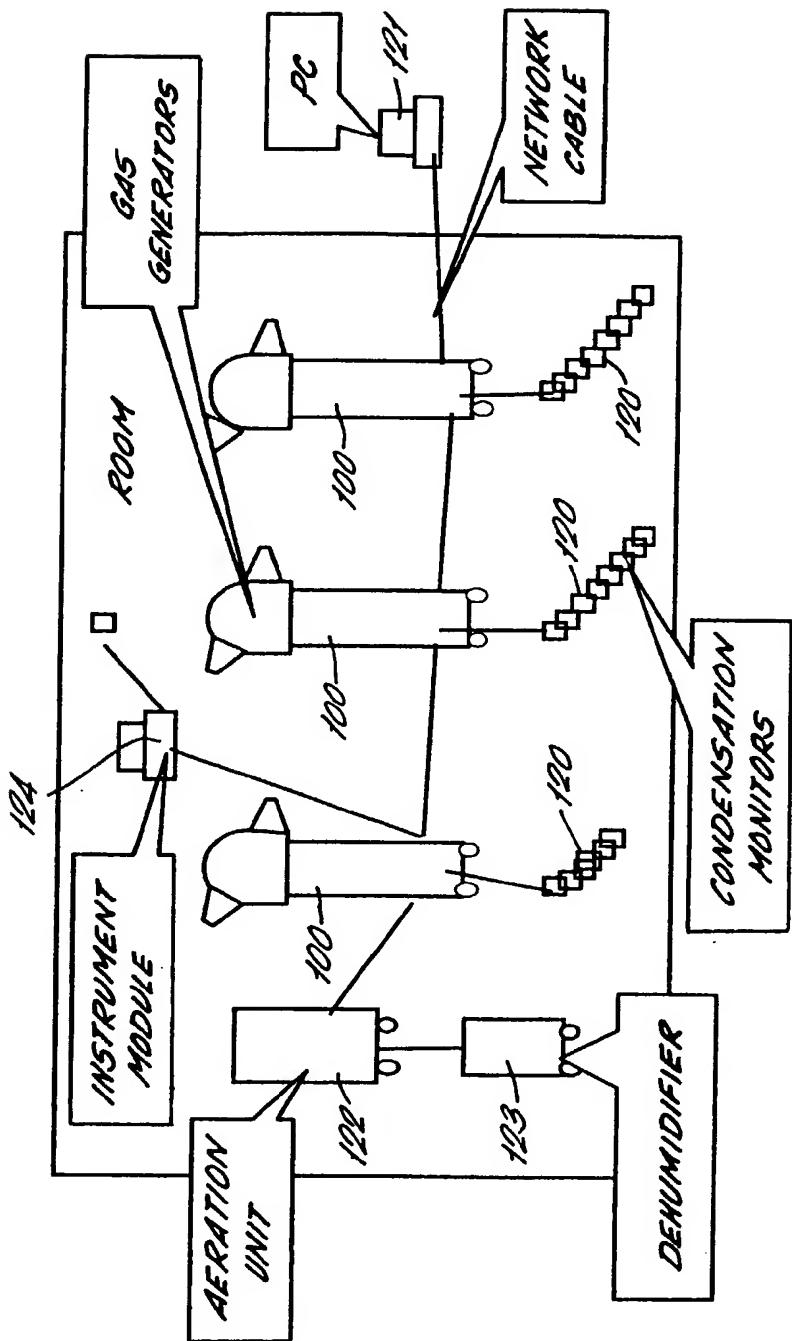


FIG. 11.



## INTERNATIONAL SEARCH REPORT

Int	ial Application No
PCT/GB 03/01386	

<b>A. CLASSIFICATION OF SUBJECT MATTER</b>		
IPC 7	A61L2/18	A61L2/20
		A61L2/24

According to International Patent Classification (IPC) or to both national classification and IPC

<b>B. FIELDS SEARCHED</b>
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Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61L
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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
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Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
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EPO-Internal, WPI Data, PAJ
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<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>
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Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 863 688 A (SCHMIDT WILLIAM C ET AL) 5 September 1989 (1989-09-05)  column 2, line 16 -column 3, line 34 column 3, line 64 -column 5, line 10 column 6, line 38-50; figure 1  ---  CH 689 178 A (SKAN AG) 30 November 1998 (1998-11-30) column 2, line 7-49 column 3, line 3 -column 4, line 56; claims 1,7,10; figure 1  ---  WO 02 11774 A (BIOQUELL UK LTD ;DRINKWATER JAMES LINDSAY (GB)) 14 February 2002 (2002-02-14) page 2, line 1 -page 3, line 17 page 5, line 7-12; claims; figure  ---	1,5,6, 9-14,16, 19-22  1,5,6, 9-18
A	-/-	

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

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- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*&\* document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
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15 July 2003	22/07/2003
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Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer
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Maremotti, M
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## INTERNATIONAL SEARCH REPORT

Inte al Application No

PCT/GB 03/01386

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 096 265 A (SCHMIED CHRISTIAN ET AL) 1 August 2000 (2000-08-01) column 1, line 35 -column 2, line 47 column 3, line 1-3 column 3, line 39-49; figure 1 -----	

## INTERNATIONAL SEARCH REPORT

Inte	nal Application No
PCT/GB 03/01386	

Patent document cited in search report		Publication date		Patent family member(s)		Publication date
US 4863688	A	05-09-1989	CA CN DE EP JP JP WO US	1297404 C 87108360 A 3778355 D1 0294418 A1 1502722 T 2722228 B2 8804939 A1 4935371 A		17-03-1992 07-12-1988 21-05-1992 14-12-1988 21-09-1989 04-03-1998 14-07-1988 19-06-1990
CH 689178	A	30-11-1998	CH	689178 A5		30-11-1998
WO 0211774	A	14-02-2002	GB AU WO	2367494 A 7574301 A 0211774 A1		10-04-2002 18-02-2002 14-02-2002
US 6096265	A	01-08-2000	AT AU AU BR CA CN DE DE DK EP ES GR JP NO NZ RU US ZA	186696 T 715413 B2 6200796 A 9603385 A 2183090 A1 1146916 A , B 69605159 D1 69605159 T2 758611 T3 0758611 A1 2140019 T3 3032502 T3 9104418 A 963325 A 299099 A 2167799 C2 5997827 A 9606774 A		15-12-1999 03-02-2000 13-02-1997 19-05-1998 12-02-1997 09-04-1997 23-12-1999 16-11-2000 08-05-2000 19-02-1997 16-02-2000 31-05-2000 22-04-1997 12-02-1997 26-06-1998 27-05-2001 07-12-1999 09-02-1998